

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (currently amended): A pharmaceutical dosage form comprising a fill material sealed in capsule shells wherein the fill material comprises (a) ~~a selective cyclooxygenase-2 inhibitory drug of low water solubility celecoxib~~ and (b) ~~at least one pharmaceutically acceptable sulfite compound sodium metabisulfite~~, wherein the capsule shells comprise gelatin, and wherein the ~~at least one pharmaceutically acceptable sulfite compound sodium metabisulfite~~ is present in a total sulfite amount sufficient to inhibit gelatin cross-linking and/or pellicle formation in the capsule shells upon storage of the dosage form.

Claim 2 (cancelled).

Claim 3 (currently amended): The dosage form of Claim claim 1 wherein the ~~at least one pharmaceutically acceptable sulfite compound sodium metabisulfite~~ is present in a total sulfite amount of not more than about 10% of the dosage form on a dry weight basis.

Claim 4 (currently amended): The dosage form of Claim claim 1 wherein the fill material further comprises at least one pharmaceutically acceptable excipient selected from the group consisting of free radical-scavenging antioxidants, sweeteners, preservatives, wetting agents, buffering agents, flavoring agents, colorants, stabilizers, fragrances, glidants, crystallization inhibitors, adhesives, lubricants, and thickeners.

Claim 5 (currently amended): The dosage form of Claim claim 1 further comprising at least one free radical-scavenging antioxidant compound selected from the group consisting of ~~α-tocopherols, ascorbic acids, ascorbates, palmitates, butylated hydroxyanisoles, butylated hydroxytoluenes, fumaric acids, fumarates, hypophosphorous acids, malic acids, and alkyl gallates α-tocopherol (vitamin E), ascorbic acid (vitamin C) and salts thereof including sodium ascorbate and ascorbic acid palmitate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), fumaric acid and salts thereof, hypophosphorous acid, malic acid, alkyl gallates, sodium sulfite, sodium bisulfite and sodium metabisulfite.~~

Claim 6 (currently amended): The dosage form of Claim claim 5 wherein the at least one free radical-scavenging antioxidant is present in a total antioxidant amount of about 0.01% to about 5% of the dosage form on a dry weight basis.

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Claim 7 (withdrawn, currently amended): The dosage form of Claim claim 1 further comprising at least one sweetener compound selected from the group consisting of mannitols, propylene glycols, sodium saccharins, acesulfame Ks, neotames, and aspartames, sorbitols, sucroses, and high-fructose corn syrups.

Claim 8 (withdrawn, currently amended): The dosage form of Claim claim 1 wherein the fill material further comprises at least one preservative compound selected from the group consisting of benzalkonium chlorides, benzethonium chlorides, benzyl alcohols, chlorobutanol, phenols, phenylethyl alcohols, phenylmercuric nitrates, and thimerosal.

Claim 9 (currently amended): The dosage form of Claim claim 1 wherein the fill material further comprises at least one surfactant selected from the group consisting of benzalkonium chlorides, benzethonium chlorides, cetylpyridinium chlorides, dioctyl sodium sulfosuccinates, nonoxynol 9, nonoxynol 10, octoxynol 9, poloxamers, polyoxyethylenes (8), caprylic monoglycerides, capric monoglycerides, caprylic diglycerides, capric diglycerides, polyoxyethylene (35) castor oils, polyoxyethylene (20) cetostearyl ethers, polyoxyethylene (40) hydrogenated castor oils, polyoxyethylene (10) oleyl ethers, polyoxyethylene (40) stearates, polysorbate 20s, polysorbate 40s, polysorbate 60s, polysorbate 80s, propylene glycol laurates, sodium lauryl sulfates, sorbitan monolaurates, sorbitan monooleates, sorbitan monopalmitates, sorbitan monostearates, and tyloxapol benzalkonium chloride, benzethonium chloride, cetylpyridinium chloride, dioctyl sodium sulfosuccinate, nonoxynol 9, nonoxynol 10, octoxynol 9, poloxamers, polyoxyethylene (8) caprylic/capric mono- and diglycerides (e.g., Labrasol™ of Gattefossé), polyoxyethylene (35) castor oil, polyoxyethylene (20) cetostearyl ether, polyoxyethylene (40) hydrogenated castor oil, polyoxyethylene (10) oleyl ether, polyoxyethylene (40) stearate, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80, propylene glycol laurate, sodium lauryl sulfate, sorbitan monolaurate, sorbitan monooleate, sorbitan monopalmitate, sorbitan monostearate, tyloxapol, and mixtures thereof.

Claim 10 (currently amended): The dosage form of Claim claim 1 wherein the fill material is liquid.

Claim 11 (withdrawn, currently amended): The dosage form of Claim claim 1 wherein the fill material is self-emulsifying upon contact with gastric fluid.

Claim 12 (currently amended): The dosage form of Claim claim 1 wherein the fill material further comprises a solvent.

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Claim 13 (currently amended): The dosage form of Claim claim 12 wherein the **selective cyclooxygenase-2 inhibitory drug celecoxib** and the **at least one pharmaceutically acceptable sulfite compound sodium metabisulfite** are in solution in the solvent.

Claim 14 (currently amended): The dosage form of Claim claim 12 wherein the solvent is present in an amount of about 5% to about 95% of the dosage form on a dry weight basis.

Claim 15 (currently amended): The dosage form of Claim claim 12 wherein the solvent comprises at least one of a glycol component and a glycol ether component.

Claim 16 (currently amended): The dosage form of Claim claim 12 wherein the solvent comprises a glycol ether component having an average molecular weight of about 75 to about 1000.

Claim 17 (withdrawn, currently amended): The dosage form of Claim claim 12 wherein the solvent comprises at least one glycol ether selected from the group consisting of ethylene glycol monomethyl ethers, ethylene glycol dimethyl ethers, ethylene glycol monoethyl ethers, ethylene glycol diethyl ethers, ethylene glycol monobutyl ethers, ethylene glycol dibutyl ethers, ethylene glycol monophenyl ethers, ethylene glycol monobenzyl ethers, ethylene glycol butylphenyl ethers, ethylene glycol terpinyl ethers, diethylene glycol monomethyl ethers, diethylene glycol dimethyl ethers, diethylene glycol monoethyl ethers, diethylene glycol diethyl ethers, diethylene glycol divinyl ethers, ethylene glycol monobutyl ethers, diethylene glycol dibutyl ethers, diethylene glycol monoisobutyl ethers, triethylene glycol dimethyl ethers, triethylene glycol monoethyl ethers, triethylene glycol monobutyl ethers, and tetraethylene glycol dimethyl ethers.

Claim 18 (currently amended): The dosage form of Claim claim 12 wherein the solvent comprises at least one glycol selected from the group consisting of propylene glycols glycol, 1,3-butanediol and polyethylene glycols.

Claim 19 (currently amended): The dosage form of Claim claim 12 wherein the solvent comprises polyethylene glycol having an average molecular weight of about 100 to about 10,000.

Claim 20 (currently amended): The dosage form of Claim claim 12 further comprising at least one co-solvent selected from the group consisting of alcohols, oleic acid triglycerides, linoleic acid triglycerides, caprylic triglycerides, capric triglycerides, caprylic monoglycerides, capric monoglycerides, caprylic diglycerides, capric diglycerides, polyoxyethylene caprylic glycerides, polyoxyethylene capric glycerides, propylene glycol fatty acid esters, polyoxyethylene (35) castor oils, polyoxyethylene glyceryl trioleates, lower alkyl esters of a fatty acid, and water.

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Claims 21-23 (cancelled).

Claim 24 (currently amended): The dosage form of Claim 23 claim 1 wherein the celecoxib is present in an amount of about 10 to about 400 mg.

Claim 25 (currently amended): The dosage form of Claim claim 1 wherein the capsule shells are hard gelatin capsule shells.

Claim 26 (currently amended): The dosage form of Claim claim 1 wherein the capsule shells are soft gelatin capsule shells.

Claim 27 (currently amended): The dosage form of Claim claim 1 wherein each of the gelatin capsule shells have a fill capacity of about 0.1 ml to about 2 ml.

Claims 28-29 (cancelled).

Claim 30 (currently amended): The dosage form of Claim claim 1 wherein the at least one pharmaceutically acceptable sulfite compound is sodium metabisulfite and/or sodium bisulfite is present in a total sulfite amount of about 0.5% to about 5% on a dry weight basis; wherein the fill material further comprises hydroxypropyl methylcellulose and/or polyethylene glycol, wherein the selective cyclooxygenase-2 inhibitory drug is celecoxib present in an amount of about 10 to about 400 mg, and wherein the capsule shells are soft gelatin capsule shells.

Claim 31 (cancelled).